

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

EXELA PHARMA SCIENCES, LLC, *et al.*,

Plaintiffs,

V.

DAVID J. KAPPOS, Under Secretary of
Commerce for Intellectual Property and
Director of the United States Patent and
Trademark Office,

UNITED STATES PATENT AND
TRADEMARK OFFICE,

Defendants,

and

SCR PHARMATOP and CADENCE
PHARMACEUTICALS, INC.

Intervenors-Defendants

Civil Action No. 1:12-cv-00469
(LO/JFA)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' AND INTERVENORS'
JOINT MOTION FOR RECONSIDERATION

Pursuant to Local Rule 7(F)(1), Defendants and Intervenor, through their undersigned counsel, hereby respectfully submit the instant memorandum of law in support of their joint motion for reconsideration in the above-captioned action.

INTRODUCTION

The only issue that this Court must address in determining whether Plaintiffs Exela Pharma Sciences, LLC, Exela PharmaSci, Inc., and Exela Holdings, Inc. (“Plaintiffs”) have brought a timely cause of action under the Administrative Procedure Act (“APA”) is the date on which the six-year statute of limitations in 28 U.S.C. § 2401(a) commenced. In denying

Defendants' motion to dismiss, this Court held that the statute of limitations commenced on the date of Plaintiffs' alleged injury, *i.e.*, when Intervenor Cadence Pharmaceuticals, Inc. and SCR Pharmatop ("Intervenor") sued them for patent infringement in 2011. However, respectfully, under the Fourth Circuit's recent decision in *Hire Order Ltd. v. Marianos*, -- F.3d --, 2012 WL 4950863 (4th Cir. Oct. 18, 2012), that decision was in error.

In *Hire Order*, the Fourth Circuit held that for purposes of APA actions, the six-year statute of limitations in § 2401(a) begins to run on the date of "final agency action" regardless of whether the plaintiff is injured by that action immediately or at a later date. And here, the only "final agency actions" that Plaintiffs challenge are a 2003 United States Patent and Trademark Office ("USPTO") decision reviving Intervenor's PCT/FR01/01749 application ("2003 Revival Decision") and the 2000 amendment of 37 C.F.R. § 1.137(b), which USPTO applied to Intervenor's petition to revive that application. Because both of these "final agency actions" occurred more than six years ago, Plaintiffs' action is untimely.

Moreover, Plaintiffs' petition to reconsider the 2003 Revival Decision did not restart the limitations clock for purposes of this action. USPTO's 2012 Letter, which responded to Plaintiffs' petition by explaining that reconsideration of the 2003 Revival Decision would violate USPTO procedural rules and regulations, as well as the Patent Act, cannot trigger the statute of limitations because it does not address the underlying issue in this case—*i.e.*, whether the revival of Intervenor's PCT application pursuant to § 1.137(b) was consistent with 35 U.S.C. § 371(d). Plaintiffs can point to no final agency action taken by USPTO *against Plaintiffs*. Accordingly, this Court should grant Defendants' and Intervenor's joint motion for reconsideration and dismiss this case.

FACTUAL BACKGROUND

I. THE '218 PATENT

On June 6, 2000, SCR Pharmatop (“Pharmatop”), a French company, filed French patent application FR 00 07231 for a “new method for obtaining aqueous formulations with active principles susceptible to oxidation and the aqueous solutions thus obtained.” *See* A.R. at A293.¹ A year later, on June 6, 2001, Pharmatop filed in the United States international patent application number PCT/FR01/01749 claiming priority to FR 00 07231. *Id.* at A205. United States patent application number 10/332,060 was the national stage application for PCT/FR01/01749 and ultimately issued in the United States as the '218 patent on January 31, 2006. *Id.* at A1.

II. ABANDONMENT AND REVIVAL OF PCT/FR01/01749

Pharmatop was required to fulfill the paperwork and fee requirements of 35 U.S.C. § 371(c) by December 6, 2002—*i.e.*, 30 months from the filing of FR 00 07231—to avoid abandonment of the PCT/FR01/01749 application. *See* 35 U.S.C. § 371(d); 37 C.F.R. § 1.495(b). Pharmatop failed, however, to make the required submissions by that date, and the application became abandoned. *See* A.R. at 219-20.

Less than one month later, on or around January 2, 2003, Pharmatop filed a petition pursuant to 37 C.F.R. § 1.137(b) seeking to revive PCT/FR01/01749 as to the United States. *Id.* In its submission, Pharmatop stated that the entire delay in meeting the national stage requirements was “unintentional.” *Id.* On April 25, 2003, USPTO granted Pharmatop’s petition, finding that “all requirements under 37 C.F.R. § 1.137(b) ha[d] been met.” *See id.* at A15.

¹In order to avoid including an additional set of exhibits, to the extent possible, citations will be to the Administrative Record (“A.R.”) filed on September 25, 2012. *See* Dkt. No. 34.

III. '218 PATENT INFRINGEMENT LITIGATION

Cadence Pharmaceuticals, Inc. (“Cadence”)² holds NDA No. 022450 for OFIRMEV®, an intravenous formulation of acetaminophen available in the United States. *See* Dkt. No. 8-1, Gov’t Exh. 2, ¶ 30. The Orange Book lists U.S. Patent No. 6,028,222 (“’222 patent”) and the ’218 patent for OFIRMEV®. *Id.* ¶ 31; *see also* Compl. ¶ 47. On or around July 7, 2011, Exela Pharma Sciences (“EPS”) submitted ANDA No. 20-3092 to the FDA seeking approval to engage in the commercial manufacture, use, sale, or offer for sale, and/or importation of Acetaminophen Injection, 10 mg/mL, 100 mL vials (“Exela Generic”), as a generic version of OFIRMEV®. *See* Dkt. No. 8-1, Gov’t Exh. 2, ¶ 42. EPS submitted paragraph IV certifications with respect to the Orange Book-listed ’218 and ’222 patents. *See id.* ¶ 44.

On August 8, 2011—over eight years after USPTO granted Pharmatop’s 37 C.F.R. § 1.137(b) petition to revive PCT/FR01/01749—Pharmatop and Cadence filed suit in the United States District Court for the District of Delaware against Plaintiffs here and other defendants alleging infringement of both the ’218 patent and the ’222 patent. Cadence and Pharmatop claim that the submission of the ANDA application—as well as any commercial manufacture, import, use, offer for sale, or sale of the Exela Generic—constitutes an infringement of the patents-in-suit. *Id.* ¶ 47. That lawsuit is currently nearing the completion of fact discovery, and a 10-day bench trial is scheduled for May 20, 2013.

²Pharmatop granted an exclusive license to the ’218 patent to Bristol-Myers Squibb (“BMS”), and BMS in turn granted Cadence an exclusive sublicense to the ’218 patent. *See* Dkt. No. 8-1, Gov’t Exh. 2, ¶ 29.

IV. PLAINTIFFS' PETITION FOR RECONSIDERATION PURSUANT TO §§ 1.181 AND 1.182

On November 11, 2011, Plaintiffs petitioned USPTO pursuant to 37 C.F.R. §§ 1.181 and 1.182 to “reconsider and withdraw its petition decision reviving abandoned U.S. patent application no. 10/332,060, which ultimately issued as U.S. Patent No. 6,992,218.” *See* A.R. at A3 - A14. On February 17, 2012, USPTO issued a Letter stating that the Patent Act and USPTO regulations do not provide for a nonparty’s challenge to an *ex parte* patent proceeding:

As a third party to an *ex parte* proceeding, petitioner is not in a position to demand that the USPTO act to vacate a prior decision unless specifically authorized by statute or regulation. In particular, neither the patent statute nor its implementing regulations, confer a right upon a third party to intervene or otherwise challenge the Office’s decision to revive the international application. Information submitted to the Office regarding a patent that is not in reexamination must be consistent with 35 USC § 301, 37 CFR §§ 1.322 or 1.501, or the standards discussed in MPEP § 2207. The action requested by the third party here is not specifically authorized by statute or regulation, and the communication is not a proper submission under 35 USC § 301, 37 CFR §§ 1.322 or 1.501, or the standards discussed in MPEP § 2207. As petitioner lacks standing, the Office will not act as requested.

Id. at A1. Accordingly, USPTO “decline[d] to take any action on petitioner’s request” and returned the petition fee. *Id.* at A2. USPTO also determined that the petition would not be made part of record in the application file. *Id.*

PROCEDURAL BACKGROUND

Plaintiffs filed this lawsuit on April 26, 2012. On June 25, 2012, Defendants filed a motion to dismiss Plaintiffs’ complaint, arguing that it was untimely under 28 U.S.C. § 2401(a), that Plaintiffs lacked standing, and that Plaintiffs’ claims were unreviewable under the Federal Circuit’s decision in *Aristocrat Techs. Australia Pty Ltd. v. Int’l Game Tech.*, 543 F.3d 657 (Fed. Cir. 2008). *See* Dkt. Nos. 7-8. This Court denied Defendants’ motion on August 22, 2012. *See Exela Pharma Scis., LLC v. Kappos*, No. 1:12-cv-469, 2012 WL 3638552, at *1 (E.D. Va. Aug.

22, 2012). With respect to timeliness, the Court held in a Memorandum Opinion that both Plaintiffs' challenge to the nine-year-old revival decision, as well as their facial challenge to § 1.137(b)—which was amended to establish procedures for revival under an unintentional delay standard twelve years ago—were timely because Plaintiffs were injured within six years of this lawsuit when Intervenor filed suit against them in Delaware. *Id.* at *1-*2.

Pursuant to an Agreed Order entered by the Court on September 14, 2012, Dkt. No. 27, Plaintiffs filed a motion for summary judgment on October 16, 2012. Dkt. No. 41. Two days later, on October 18, 2012, the Fourth Circuit issued a published decision in *Hire Order Ltd. v. Marianos*, -- F.3d --, 2012 WL 4950863 (4th Cir. Oct. 18, 2012). That decision provides new, binding authority on the application of § 2401(a) to challenges to final agency actions under the APA. On November 2, 2012, in light of *Hire Order*, this Court granted Defendants' motion for a continuance of the merits briefing schedule such that Defendants and Intervenor could file this motion for reconsideration. Dkt. No. 47.

STANDARD OF REVIEW

This Court has held that “[t]he Federal Rules of Civil Procedure expressly provide a district court discretion to revise interlocutory orders prior to final judgment.” *Perry-Bey v. City of Norfolk, Va.*, 678 F. Supp. 2d 348, 374 (E.D. Va. 2009) (citing Fed. R. Civ. P. 54(b) (“[A]ny order or other decision, however designated, that adjudicates fewer than all the claims . . . may be revised at any time before the entry of [final] judgment . . .”). “In considering motions for reconsideration of such interlocutory orders, a district court is not required to apply ‘the strict standards applicable to motions for reconsideration of a final judgment’ under Fed. R. Civ. P. 59(e) because a district court ‘retains the power to reconsider and modify its interlocutory

judgments . . . at any time prior to final judgment when such is warranted.” *Id.* (quoting *Am. Canoe Ass’n v. Murphy Farms, Inc.*, 326 F.3d 505, 514-15 (4th Cir. 2003)). That is, “[t]he power to reconsider the interlocutory judgment is committed to the discretion of the district court,” *id.*, and “therefore plaintiff is not required to make a showing of extraordinary circumstances,” *Netscape Commc’ns Corp. v. ValueClick, Inc.*, 704 F. Supp. 2d 544, 546-47 (E.D. Va. 2010). “Instead, the goal . . . ‘is to reach the correct judgment under law.’” *Id.* (quoting *Am. Canoe Ass’n*, 326 F.3d at 514-15).

ARGUMENT

I. HIRE ORDER IS BINDING ON THE ISSUE OF TIMELINESS.

Federal district courts have exclusive jurisdiction over actions “arising under any Act of Congress relating to patents” 28 U.S.C. § 1338(a), and all such cases are appealed to the United States Court of Appeals for the Federal Circuit, 28 U.S.C. § 1295(a). Thus, the Federal Circuit will apply its “own law to both substantive and procedural issues intimately involved in the substance of enforcement of [a] patent right.” *O2 Micro Int’l Ltd. v. Monolithic Power Systems, Inc.*, 467 F.3d 1355, 1364 (Fed. Cir. 2006) (quoting *Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1363 (Fed. Cir. 2004)). However, the Federal Circuit “defers to the law of the regional circuits on matters of procedural law that do not implicate issues of patent law, *such as statute of limitations rulings.*” *Landmark Screens, LLC v. Morgan, Lewis, & Bockius, LLP*, 676 F.3d 1354, 1361-62 (Fed. Cir. 2012) (emphasis added) (internal quotations omitted). Thus, although Plaintiffs’ APA challenge to USPTO’s decision to revive Intervenor’s PCT application under 35 U.S.C. § 371(d) implicates the Patent Act, Fourth Circuit authority—now including *Hire*

Order—is binding on the question of the timeliness of Plaintiffs’ APA claims, and this Court’s decision on timeliness must be consistent with *Hire Order*.

II. THIS COURT SHOULD GRANT DEFENDANTS’ AND INTERVENORS’ MOTION FOR RECONSIDERATION.

In light of *Hire Order*, this Court should grant Defendants’ and Intervenor’s motion for reconsideration and dismiss Plaintiffs’ suit. Respectfully, this Court’s conclusion that § 2401(a)’s six-year statute of limitations began to run when Plaintiffs’ suffered an injury in fact—*i.e.*, when Intervenor sued Plaintiffs for patent infringement in the District of Delaware in 2011—is directly contrary to the holding of *Hire Order*. Moreover, USPTO’s Letter response to Plaintiffs’ reconsideration petition does not render their suit timely as Plaintiffs’ reconsideration petition was improper, and the Letter did not address the merits of Plaintiffs’ claims here.

A. This Court’s Decision on Timeliness Is Inconsistent with *Hire Order*.

1. “[E]very civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action first accrues.” 28 U.S.C. § 2401(a). Previously, the Fourth Circuit had held that this six-year statute of limitations applies to APA actions, and that an APA action accrues on the date of the “final agency action.” *Jersey Heights Neighborhood Ass’n v. Glendening*, 174 F.3d 180, 186 (4th Cir. 1999); *see also Harris v. FAA*, 353 F.3d 1006, 1010 (D.C. Cir. 2004). In *Hire Order*, the Fourth Circuit for the first time held that for purposes of APA actions, the six-year statute of limitations in § 2401(a) begins to run on the date of “final agency action” regardless of whether the plaintiff is injured by that action at a later date.

In that case, the appellants—who did not become federal firearms licensees until 2008—raised a pre-enforcement challenge to a 1969 revenue ruling which limits the ability of

federal firearms licensees to sell firearms at out-of-state gun shows. *Hire Order*, 2012 WL 4950863, at *1. Before Judge Hilton, the appellants had argued that their claims were timely “because their right to file a civil action did not accrue until they obtained their federal firearms licenses in 2008.” *Hire Order Ltd. v. Domenech*, No. 1:10-cv-1464, 2011 WL 2144537, at *3 (E.D. Va. May 26, 2011). Judge Hilton rejected this argument, dismissing the suit as untimely. *See id.* On appeal, the appellants again contended that denying them the right to challenge the 1969 revenue ruling would “approve the absurd result” that the only persons able to challenge it were those injured within six years after it was made. *Hire Order Ltd. v. Marianos*, No. 11-1802, Appellant’s Br. at 10.³

The Fourth Circuit disagreed. First, citing *Jersey Heights* and *Franklin v. Massachusetts*, 505 U.S. 788 (1992), the Fourth Circuit reiterated the well-settled APA principle that “[a] cause of action governed by § 2401(a) accrues or begins to run at the time of ‘final agency action.’” *Hire Order*, 2012 WL 4950863, at *2 (citing *Jersey Heights*, 174 F.3d at 186; *Franklin*, 505 U.S. at 797). For purposes of a challenge to an agency regulation, the Court found that “the limitations period begins to run when the agency publishes the regulation.” *Id.* (quoting *Dunn-McCampell Royalty Interest, Inc. v. Nat’l Park Serv.*, 112 F.3d 1283, 1287 (5th Cir. 1997)).

The court then rejected the argument—which is nearly identical to the argument raised by Plaintiffs here—that the statute of limitations could not begin running within six years of “final agency action” if appellants were not even in existence during that time. The court concluded, “The contention of *Hire Order* and *Privott* that their cause of action did not accrue

³In full, the appellants argued in their opening brief to the Fourth Circuit: “To deny Afton and Privott the opportunity to challenge Revenue Ruling 69-59 is [sic] approve the absurd result that only a person who was licensed within six years after Revenue Ruling 69-59 was issued could challenge it.” *Hire Order Ltd. v. Marianos*, No. 11-1802, Appellant’s Br. at 10.

until they became federally licensed firearms dealers in 2008 *utterly fails.*” *Id.* (emphasis added). In other words, although the appellants were not injured by—nor even affected by—the revenue ruling within six years of 1969, the Court found that the appellants’ action was untimely. In reaching that conclusion, the Court noted that the cases relied upon by the appellants—including *Bay Area Laundry & Dry Cleaning Pension Trust Fund v. Ferbar Corp. of California, Inc.*, 522 U.S. 192, 201 (1997)—“offer no support for their position.” *Id.* As such, although *Hire Order* addressed only a purely facial challenge, its holding is not so limited.

2. In denying Defendants’ motion to dismiss here on timeliness grounds, this Court held the opposite. Plaintiffs have alleged that USPTO’s 2003 decision to revive Intervenor’s PCT application pursuant to 37 C.F.R. § 1.137(b) was contrary to 35 U.S.C. § 371(d) and thus arbitrary and capricious under the APA. Section 1.137(b)—which provides for the revival of abandoned patent applications under an “unintentional delay” standard—was originally enacted in 1982 and amended in 2000 to establish procedures for revival under that standard. Therefore, the only “final agency actions” related to Plaintiffs’ substantive claims are the amendment of § 1.137(b) in 2000 and the 2003 Revival Decision applying § 1.137(b) to revive the PCT/FR01/01749 patent application, both of which occurred more than six years before this lawsuit.

Notwithstanding the fact that Plaintiffs cannot point to any final agency action in the last six years related to the merits of their APA claim here, Plaintiffs argued that the statute of limitations did not begin to accrue until they were injured in 2011, and that in fact, the statute of limitations could not have started running against them at the time of the 2003 Revival Decision because they were not even in existence at that time. This Court agreed, holding:

The parties dispute when Plaintiffs’ “right of action first accrue[d].” Defendants argue that Plaintiffs’ [sic] untimely filed their lawsuit nine years after the PTO’s 2003 revival decision. However, *Plaintiffs could not have filed a lawsuit in federal court until they had suffered an injury in fact*. Plaintiffs’ alleged injury occurred in 2011, when the PTO’s allegedly improper revival decision enabled the ‘218 licensee to file an infringement action against Plaintiffs. *Plaintiffs could not have challenged the PTO’s revival decision before the decision caused injury to the Plaintiffs in 2011. Plaintiffs’ 2012 challenge is timely.*

Exela Pharma Scis., LLC v. Kappos, No. 1:12-cv-469, 2012 WL 3638552, at *1 (E.D. Va. Aug. 22, 2012) (emphases added) (internal citations omitted). In other words, the Court determined that the date of Plaintiffs’ injury—*i.e.*, the date of Intervenor’s Delaware lawsuit alleging infringement of the revived patent—was the operative date for commencing the statute of limitations on Plaintiffs’ APA challenge to the 2003 Revival Decision, rather than the date of final agency action.

The Court then went on to hold that Plaintiffs’ *facial challenge* to 37 C.F.R. § 1.137(b)—which was promulgated in its current form twelve years prior to this lawsuit—was timely. *Id.* at *2. Although Plaintiffs have since denied raising a facial challenge in this lawsuit, their complaint is entitled “Complaint for Declaratory and Injunctive Relief and *Petition for Review of Rulemaking*,” and Count IV is entitled “Unlawful Rules and Regulations.”⁴ The Complaint also asks, in the Request for Relief, that this Court “[i]ssue a declaratory judgment or other order holding that the USPTO *rules and regulations* allowing for the revival of an international patent application under the ‘unintentional’ standard are unlawful.” As a result, this Court addressed these claims and found that they were not time-barred.

⁴Plaintiffs’ Complaint did not even appear to identify, however, the precise “Rules and Regulations” that they were challenging.

In so holding, the Court noted that under the Ninth Circuit’s decision in *Wind River Mining Corp. v. United States*, 946 F.2d 710 (9th Cir. 1991), “an exception to th[e 2000] accrual date exists when the challenger alleges that the agency applied the statute in a way that exceeds constitutional or statutory authority.” *Exela Pharma Scis.*, 2012 WL 3638552, at *2 (citing *Wind River*, 946 F.2d at 715). The Court then explained:

[T]he Ninth Circuit found that plaintiffs were not time barred from bringing a suit fourteen years after the agency’s initial decision *applying a regulation* when the plaintiffs “*could have had no idea*” at the time the agency applied the regulation that the agency’s decision would affect them. Here, the PTO’s revival decision did not affect the Plaintiffs until 2011 when the PTO’s allegedly erroneous decision permitted the ‘218 patent licensee to file an infringement action against them. Plaintiffs’ challenge is timely.

Id. (emphases added) (citing *N. Cnty. Cmty. Alliance, Inc. v. Salazar*, 573 F.3d 738, 743 (9th Cir. 2009)). That is, the Court determined that under the Ninth Circuit’s *Wind River* and *Northern County Community Alliance* decisions, Plaintiffs’ facial challenge was timely because § 1.137(b) was applied against Intervenor, and Plaintiffs were injured by that application within six years of this lawsuit.

3. These conclusions are plainly inconsistent with *Hire Order*. First, Plaintiffs’ challenge to the 2003 Revival Decision is untimely. *Hire Order* addressed the argument expressly raised here—*i.e.*, that regardless of the date of final agency action, the six-year statute of limitations does not start running until the plaintiff is injured—and rejected it.

In finding Plaintiffs’ challenge to the 2003 Revival Decision timely, this Court relied upon *Franklin v. Massachusetts*, 505 U.S. 788 (1992), and *Golden & Zimmerman, L.L.C. v. Domenech*, 599 F. Supp. 2d 702 (E.D. Va. 2009). See *Exela Pharma Scis.*, 2012 WL 3638552, at *2. But the *Hire Order* court cited *Franklin* in defining “final agency action” and still dismissed the case. *Hire Order*, 2012 WL 4950863, at *2. Indeed, both *Franklin* and *Golden &*

Zimmerman address the definition of “final agency action” without addressing what event triggers the six-year statute of limitations in § 2401(a), and *Hire Order* makes clear that neither of these cases support Plaintiffs’ argument that the statute of limitations begins to run at the time of Plaintiffs’ injury.

This Court also cited *Bay Area Laundry & Dry Cleaning Pension Trust Fund v. Ferbar Corp. of California, Inc.*, 522 U.S. 192, 201 (1997), in finding Plaintiffs’ challenge to the 2003 Revival Decision timely. But in *Hire Order*, the Fourth Circuit held that *Bay Area Laundry* did not support the appellants’ argument that the statute of limitations commenced when they were injured long after final agency action. *Hire Order*, 2012 WL 4950863, at *2; *see also Cordis Corp. v. Kappos*, No. 1:11-cv-127, 2011 WL 4369118, at *4 (E.D. Va. Sept. 6, 2011) (refusing to find that the plaintiff’s claim was timely under the reasoning of *Bay Area Laundry* and holding that “[t]he Court rejects Plaintiff’s argument that the cause of action did not accrue until its patents were submitted for reexamination”).⁵ Indeed, as explained in Defendants’ motion to dismiss briefs, *see* Dkt. No. 12 at 4, *Bay Area Laundry* (a) concerned the Employee Retirement Income Security Act of 1974 (“ERISA”), not administrative law and not the APA; (b) was litigated by two private parties without involving the Federal Government or its waiver of sovereign immunity; and (c) does not mention, much less consider, the relevant statute of limitations in this case, 28 U.S.C. § 2401(a), and moreover construes statutory language different

⁵Plaintiff in *Cordis* had argued that *Bay Area Laundry* was controlling and that “[u]nder the argument that the Federal Defendants and Abbott both advance, the six-year statute of limitations period applicable to Cordis’s current APA cause of action should be deemed to commence on the date of the agency final action *without regard to whether Cordis could have brought suit at that time*. Nothing in § 2401(a) remotely suggests such an ‘odd result.’” *Cordis Corp. v. Kappos*, No. 1:11cv127, Pl. Reply Br. at 10-11 (emphasis in original).

from that found in § 2401(a). Thus, as the *Hire Order* court found, it is not controlling in this case.

This Court's conclusion that Plaintiffs' facial challenge was timely under the Ninth Circuit's decisions in *Wind River* and *North County Community Alliance* conflicts with *Hire Order* for the same reasons. The Court correctly observed that under *Wind River* and other circuit decisions, a plaintiff can challenge an agency regulation over six years old if that challenge is brought in conjunction with an as-applied challenge to new agency conduct. In light of *Hire Order*, however, this Court erred in finding that Plaintiffs' challenge to USPTO's application of § 1.137(b) to Intervenor was timely because Plaintiffs were not injured by the decision until Intervenor sued them for infringement in 2011. Again, under the reasoning of *Hire Order*, the date of final agency action, and not the date of Plaintiffs' injury, is the operative date for statute of limitations purposes. Thus, to the extent the Ninth Circuit's non-binding *North County Community Alliance* decision ever stood for the proposition that the statute of limitations commences on the date of injury—and Defendants and Intervenor maintain that it misapplied the sound reasoning of *Wind River*—*Hire Order* directly contradicts it, and any facial challenge raised by Plaintiffs is untimely.

4. *Hire Order* is not distinguishable from this case because it addressed only a purely facial challenge. Indeed, this Court's holding that the statute of limitations on Plaintiffs' APA action began to run at the time of Plaintiffs' injury rather than at the time of final agency action conflicts with *Hire Order*, regardless of whether Plaintiffs raised a facial challenge. Put differently, the holding and reasoning of *Hire Order* are not limited to the specific type of challenge presented there—in *Hire Order*, the final agency action challenged was the

promulgation of the 1969 revenue ruling, and here it is the 2003 Revival Decision, and in both cases, the plaintiffs' claims were untimely even though the plaintiffs were injured by those final agency actions within six years of the suit. Thus, even if Plaintiffs have not raised a facial challenge to USPTO's regulations in this lawsuit, their suit is thus untimely because they can point to no final agency action applying those regulations within the last six years.

Furthermore, unlike the plaintiffs in *Wind River*, the regulation at issue here was never applied by USPTO *against Plaintiffs*. Indeed, Plaintiffs have not challenged any final agency action applying § 1.137(b) *against Plaintiffs* in the last six years. *Cf. Wind River*, 946 F.2d at 715 ("We hold that a substantive challenge to an agency decision alleging lack of agency authority may be brought within six years of the agency's application of that decision *to the specific challenger*." (emphasis added)); *Dunn-McCampbell*, 112 F.3d at 1287 ("[T]he claimant must show some direct, final agency action *involving the particular plaintiff* within six years of filing suit." (emphasis added)); *Hire Order*, 2011 WL 2144537, at *3 ("Plaintiffs' Complaint does not identify any final agency action regarding application of the Revenue Ruling directed at them within the past six years."). And Plaintiffs do not even bring a pre-enforcement challenge like the appellants in *Hire Order*. As such, despite their arguments to the contrary, Plaintiffs' challenge here is, in fact, a facial challenge to the agency's application of § 1.137(b) to *all* PCT applications abandoned under § 371(d), regardless of that provision's application against Plaintiffs. Thus, even under a very narrow reading of *Hire Order*, Plaintiffs' suit is untimely, and this Court should grant Defendants' and Intervenor's motion for reconsideration.

B. Plaintiffs' Purported Challenge to USPTO's 2012 Letter Does Not Render Their Challenges to the 2003 Revival Decision and § 1.137(b) Timely.

In a footnote in its Memorandum Opinion, this Court stated that it did not examine whether USPTO's 2012 Letter affected the timeliness of Plaintiffs' claims because the date of Plaintiffs' injury triggered the statute of limitations. It explained:

Plaintiffs claim that the limitations period began in 2012, after they exhausted their administrative remedies by submitting a letter to the PTO challenging the PTO's revival decision. The PTO argues that their response to Plaintiffs' letter did not constitute an agency action because the agency did not deny, but rather refused to consider, Plaintiffs' request. The Court need not decide whether the statute of limitations commenced with the 2011 infringement suit or the 2012 letter to the PTO. The '218 patent licensee filed its infringement action against Plaintiffs in 2011. Plaintiffs filed this lawsuit in 2012—well within the six-years from the date of that action.

Exela Pharma Scis., 2012 WL 3638552, at *2. As explained *supra*, however, under *Hire Order*, the statute of limitations did not begin running on the date of Plaintiffs' injury. And as explained in Defendants' motion to dismiss briefs, USPTO's 2012 Letter response to Plaintiffs' reconsideration petition did not restart the clock for statute of limitations purposes because it did not address the issue raised by Plaintiffs here—*i.e.*, whether § 1.137(b) applies to PCT application revivals under § 371(d).

As an initial matter, although Plaintiffs' Complaint initially attempts to cast USPTO's Letter response as the basis of this lawsuit, *see* Compl. ¶¶1-2, in fact, the only actual relief sought by Plaintiffs concerns the 2003 Revival Decision itself, as well as USPTO's "rules and regulations allowing for revival of abandoned international patent applications under the 'unintentional' standard," *see id.* ¶¶ 54-77 (Counts I-IV). In other words, Plaintiffs' seek to strike down the 2003 Revival Decision based on USPTO's application of § 1.137(b) to PCT revival applications. They are not challenging the USPTO's decision, pursuant to its own

procedural rules and regulations, not to reconsider a third party collateral attack on an international patent application revival decision.

More specifically, in its Letter, USPTO refused to reconsider the 2003 Revival Decision because Plaintiffs, as third parties to the *ex parte* revival proceeding, were not authorized by regulation or statute to challenge the revival decision:

As a third party to an *ex parte* proceeding, petitioner is not in a position to demand that the USPTO act to vacate a prior decision unless specifically authorized by statute or regulation. In particular, neither the patent statute nor its implementing regulations, confer a right upon a third party to intervene or otherwise challenge the Office's decision to revive the international application. Information submitted to the Office regarding a patent that is not in reexamination must be consistent with 35 USC § 301, 37 CFR §§ 1.322 or 1.501, or the standards discussed in MPEP § 2207. The action requested by the third party here is not specifically authorized by statute or regulation, and the communication is not a proper submission under 35 USC § 301, 37 CFR §§ 1.322 or 1.501, or the standards discussed in MPEP § 2207.

See A.R. at A1. USPTO went on to explain that the decision not to reconsider Plaintiffs' petition was "consistent with well-established case law for third party filings." *Id.* (citing *Syntex (USA), Inc. v. USPTO*, 882 F.2d 1570 (Fed. Cir. 1989); *Boeing Co. v. Comm'r of Patents & Trademarks*, 853 F.2d 878 (Fed. Cir. 1988); *Hallmark Cards, Inc. v. Lehman*, 959 F. Supp. 539 (D.D.C. 1997); *Hitachi Metals, Ltd. v. Quigg*, 776 F. Supp. 3 (D.D.C. 1991)). As a result, USPTO returned the petition fee and declined even to make the petition part of the record. *Id.* at A2 (citing *Nat'l R.R. Passenger Corp. v. Nat'l Ass'n of R.R. Passengers*, 414 U.S. 453, 458 (1974) ("A frequently stated principle of statutory construction is that when legislation expressly provides a particular remedy or remedies, courts should not expand the coverage of the statute to subsume other remedies."); *Botany Worsted Mills v. United States*, 278 U.S. 282, 289 (1929) ("When a statute limits a thing to be done in a particular mode, it includes the negative of any other mode.")).

Thus, the Letter response does not constitute a timely final agency action with respect to revival of Intervenor's PCT patent application. That is, USPTO's Letter does not affirm or reject its 2003 Revival Decision, and § 1.137(b) has no bearing on the Letter's analysis; indeed, the Letter does not even mention the application of § 1.137(b) in the context of § 371(d). Instead, USPTO interpreted its own *procedural* rules and regulations—including 37 C.F.R. §§ 1.322 and 1.501 and M.P.E.P. § 2207—as well as 35 U.S.C. § 301 of the Patent Act, in finding that it was *not authorized* to reconsider the 2003 Revival Decision.

As the Letter explains, this decision not to consider Plaintiffs' challenge to the *ex parte* revival decision is not only consistent with USPTO's rules and regulations, but it is also consistent with well-settled case law regarding collateral attacks to *ex parte* patent review proceedings. USPTO recognized that Plaintiffs here challenge the long-delayed collateral effects of a USPTO decision affecting the validity of another pharmaceutical company's patent. And as explained in Defendants' motion to dismiss briefs, Dkt. No. 8 at 25-28; Dkt. No. 12 at 15-20, courts have routinely held that such decisions—which the Patent Act renders *ex parte* in nature—are insulated from APA claims by third parties. *See Syntex (USA), Inc. v. USPTO*, 882 F.2d 1570, 1574-75 (Fed. Cir. 1989) (holding in the context of § 701(a)(1) that “[t]he creation of a right or remedy in a third party to challenge a result favorable to a patent owner after *ex parte* prosecution would be *unprecedented*” and refusing to allow the third party resort to the APA); *Hallmark Cards, Inc. v. Lehman*, 959 F. Supp. 539, 544 (D.D.C. 1997) (holding “that Congress did not intend that third parties have the right to judicial review of Certificates of Correction issued by the PTO”); *Hitachi Metals, Ltd. v. Quigg*, 776 F. Supp. 3, 8 (D.D.C. 1991) (noting the *ex parte* nature of patent prosecution); *Godfredsen v. Banner*, 503 F. Supp. 642, 646 (D.D.C.

1980) (holding that judicial modification of the statutory *ex parte* process would “revolutionize patent practice”).

Moreover, addressing the merits of Plaintiffs’ request would render obsolete the reasoning of *Hire Order*. That is, if a plaintiff could get judicial review of a long-settled agency decision simply by filing a perfunctory request for reconsideration with the agency regardless of whether the agency’s statutes, regulations, and rules permitted such a request, timeliness principles—which ensure finality of agency decisions—would be meaningless. *Cf., e.g., P&V Enters. v. U.S. Army Corps of Engineers*, 516 F.3d 1021, 1023-24 (D.C. Cir. 2008) (explaining that “an otherwise stale challenge” to agency action can proceed where “the entire context demonstrates that the agency has undertaken a serious, substantive reconsideration of the existing rule”). Indeed, the Fourth Circuit in *Hire Order* questioned the ability of parties to restart the limitations clock in this manner. *See* 2012 WL 4950863, at *3 n.2 (“We note that the case on which Hire Order and Privott heavily rely in making their alternative argument [that they can restart the limitations clock by filing a petition to reconsider the revenue ruling], may not provide as fulsome authority for their position as they suggest.” (citing *NLRB Union v. FLRA*, 834 F.2d 191, 196 (D.C. Cir. 1987); *Cronin v. FAA*, 73 F.3d 1126, 1131 n.3 (D.C. Cir. 1996))). Put differently, because the Letter response does not apply § 1.137(b) against Plaintiffs or otherwise substantively reconsider the 2003 Revival Decision, it does not start a new limitations period or otherwise make timely Plaintiffs’ challenge to the underlying 2003 Revival Decision. *See, e.g., Dunn-McCampell*, 112 F.3d at 1287. And *Wind River* does not provide otherwise. There, the Ninth Circuit held that a challenge to a recent agency decision upholding a longstanding prior agency decision was timely where the agency *reconsidered the merits of that*

prior decision as applied to the plaintiffs within six years of the complaint. *Wind River*, 946 F.2d at 716. Unlike the timely agency action in *Wind River*, the USPTO Letter did not uphold or otherwise substantively address the 2003 Revival Decision such that the merits of that decision can be timely challenged here.

At most, the USPTO Letter constitutes “final agency action” regarding USPTO’s ability to consider a third party petition regarding a revival decision. Yet, Plaintiffs’ detailed, 16-page complaint contains a total of three references to such a claim, and nowhere does the Complaint even suggest how the agency acted arbitrarily and capriciously in refusing to reconsider Plaintiffs’ third party petition challenging USPTO’s *ex parte* revival decision. As such, Plaintiffs have failed even to state a claim regarding any challenge to the USPTO Letter. *See Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009) (“[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to . . . [t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements.”). Accordingly, Plaintiffs’ suit should be dismissed in its entirety.

CONCLUSION

For the foregoing reasons, this Court should grant Defendants’ and Intervenor’s motion for reconsideration and dismiss Plaintiffs’ Complaint in its entirety.

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Respectfully submitted,

<p>NEIL H. MACBRIDE</p> <p>UNITED STATES ATTORNEY</p> <p>_____/s/_____ Stephen J. Obermeier Assistant United States Attorney Justin W. Williams U. S. Attorney's Building 2100 Jamieson Avenue Alexandria, Virginia 22314 (703) 299-3785 (direct) (703) 299-3983 (fax) stephen.obermeier@usdoj.gov</p> <p>Attorneys for Defendants</p>	<p>_____/s/_____ Aaron L. Webb (VSB # 73621) Peter T. Ewald (VSB #71601) OLIFF & BERRIDGE, PLC 277 South Washington Street, Suite 500 Alexandria, Virginia 22314 Telephone: 703-836-6400 Facsimile: 703-836-2787 awebb@oliff.com pewald@oliff.com</p> <p>Local Counsel for Intervenor-Defendants Cadence Pharmaceuticals, Inc. and SCR Pharmatop</p>
<p>_____/s/_____ Kenneth Schuler (Admitted Pro Hac Vice) Marc Zubick (Admitted Pro Hac Vice) LATHAM & WATKINS LLP 233 South Wacker Drive, Suite 5800 Chicago, IL 60606 Telephone: 312-876-7700 Facsimile: 312-993-9767 kenneth.schuler@lw.com marc.zubick@lw.com</p> <p>Stephen Swinton (Admitted Pro Hac Vice) LATHAM & WATKINS LLP 12636 High Bluff Drive, Suite 400 San Diego, CA 92130 Telephone: 858-523-5400 Facsimile: 858-523-5450 steve.swinton@lw.com</p> <p>Attorneys for Cadence Pharmaceuticals, Inc.</p>	<p>_____/s/_____ Thomas Christopher Grimm (Admitted Pro Hac Vice) MORRIS, NICHOLS, ARSHT & TUNNELL LLP 1201 N. Market Street, PO Box 1347 Wilmington, DE 19899 Telephone: 302-658-9200 Facsimile: 302-425-4661 tgrimm@mnat.com</p> <p>Charles A. Weiss (Admitted Pro Hac Vice) HOLLAND & KNIGHT LLP 31 West 52nd Street New York, NY 10019 Telephone: 212-513-3200 Facsimile: 212-385-9010 charles.weiss@hklaw.com</p> <p>Attorneys for SCR Pharmatop</p>

DATED: November 6, 2012

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on November 6, 2012, I will file the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of such filing to the following:

Clarence Edward Polk , Jr.
Exela Pharma Sciences, LLC
42450 Longacre Drive
Chantilly, VA 20152
703-989-5397
Fax: 703-957-4166
Email: epolk@exela.us

By: /s/
Stephen J. Obermeier
Assistant United States Attorney
Justin W. Williams U. S. Attorney's Building
2100 Jamieson Avenue
Alexandria, Virginia 22314
(703) 299-3785 (direct)
(703) 299-3983 (fax)
stephen.obermeier@usdoj.gov

ATTORNEY FOR DEFENDANTS